

Appn. No. 09/937,706
Amd. dated February 4, 2004
Reply to Office Action of October 14, 2003

Amendments to the Claims

This listing of claims will replace all prior versions,
and listings of claims in the application:

Listing of Claims:

1 (Currently amended). A monoclonal IgG antibody (Mab) capable of binding Placental Protein 13 (PP-13) ~~with high affinity and of detecting PP-13 at a concentration of 10 pg/ml in a sandwich ELISA assay.~~

2 (Currently amended). [[A]] ~~The~~ Mab according to Claim 1 produced by a hybridoma cell selected from the group consisting of clones #26-2, 27-2-3, 215-28-3, 534-16 and 606-8-11-67 deposited under accession nos. I-2134, I-2135, I-2136, I-2137, and I-2138.

3 (Currently amended). A hybridoma clone selected from the group consisting of clones #26-2, 27-2-3, 215-28-3, 534-16 and 606-8-11-67 deposited under accession nos. I-2134, I-2135, I-2136, I-2137 and I-2138.

4 (Currently amended). An immunoassay for measuring the level of PP-13 in a biological fluid, comprising the steps of:

(One) (a) bringing said fluid into contact with a Mab according to any of Claims 1, 2, or [[16]] 18, thereby forming Mab-PP-13 complexes;

(Two) (b) exposing said complexes to a second Mab according to any of claims 1, 2, or [[16]] 18 linked to a signal-generating molecule, said second Mab being capable of binding said complexes; and

(Three) (c) providing conditions conducive to the production of a signal generated by said signal-generating molecule, the level of said signal indicating the level of PP-13 in the biological fluid,

wherein said immunoassay is capable of measuring PP-13 over at a concentration ~~range~~ of 10-500 pg/ml.

5 (Currently amended). [[An]] The immunoassay according to Claim 4, wherein said Mab in step (a) is bound to a solid phase.

Claim 6 (Cancelled).

7 (Currently amended). [[An]] The immunoassay according to either of ~~Claims 4 or 5~~ Claim 4, wherein said signal generating molecule is an enzyme.

8 (Currently amended). [[An]] The immunoassay according to either of Claims 4 or 5 Claim 4, wherein said signal generating molecule is a ligand, and step (c) of Claim 4 comprises incubating the product of step (b) with a ligand binding molecule linked to an enzyme.

9 (Currently amended). A kit for measuring the level of PP-13 in a biological fluid, comprising:

- (a) a Mab according to Claim 1;
- (b) a second antibody linked to a signal-generating molecule, wherein said second antibody is also a Mab according to Claim 1; and
- (c) PP-13 standard solutions.

10 (Currently amended). A kit for measuring the level of PP-13 in a biological fluid, comprising:

- ~~(One)~~ (a) a Mab according to any of Claims 1, 2, or [[16]] 18;
- ~~(Two)~~ (b) a second Mab according to any of Claims 1, 2, or [[16]] 18 linked to a signal-generating molecule; and
- ~~(Three)~~ (c) PP-13 standard solutions.

11 (Currently amended). [[A]] The kit according to Claim 9, wherein said signal generating molecule is an enzyme.

Claim 12 (Cancelled)

13 (Currently amended). [[A]] The kit according to
Claim [[12]] 9, wherein said signal-generating molecule ligand is
biotin and ~~said ligand binding molecule is the~~ kit further
comprises extravidin linked to an enzyme.

14 (Previously presented). A Mab according to Claim 1,
capable of detecting PP-13 at a concentration of 0.05 ng/ml in a
sandwich ELISA assay.

15 (Currently amended). [[A]] The kit according to
Claim 11, wherein said signal generating molecule is an enzyme.

16 (Currently amended). [[A]] The kit according to
Claim 11, wherein said signal generating molecule is a ligand,
and said kit further comprises a ligand binding molecule linked
to an enzyme.

17 (Currently amended). [[A]] The kit according to
Claim 16, wherein said ligand is biotin and said ligand-binding
molecule is extravidin.

18 (New). The Mab according to Claim 2 produced by the
hybridoma clone deposited under accession no. I-2135 or I-2136.

Appln. No. 09/937,706
Amd. dated February 4, 2004
Reply to Office Action of October 14, 2003

19 (New). The immunoassay according to Claim 5, wherein
said signal generating molecule is an enzyme.